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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|------------------------|------------------|
| 10/540,415 | 07/29/2005 | Christopher Scott | 08830-0349US1 | 4225 |
| 23973 | 7590 | 10/18/2007 | EXAMINER | |
| DRINKER BIDDLE & REATH | | | OGUNBIYI, OLUWATOSIN A | |
| ATTN: INTELLECTUAL PROPERTY GROUP | | | ART UNIT | PAPER NUMBER |
| ONE LOGAN SQUARE | | | 1645 | |
| 18TH AND CHERRY STREETS | | | | |
| PHILADELPHIA, PA 19103-6996 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 10/18/2007 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/540,415 | SCOTT, CHRISTOPHER |
| | Examiner | Art Unit |
| | Oluwatosin Ogunbiyi | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6-22 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 6-22 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment to the claims filed 6/24/05 has been entered into the record.
Claims 1-5 are cancelled. Claims 6-22 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I: claims 6-9 and 10-13 drawn to an expression construct for the production of recombinant polypeptides, which construct comprises an expression cassette consisting of the following elements that are operably linked: a) a promoter; b) the coding region of a DNA encoding a sortase gene product as a purification tag sequence; and c) a cloning site for receiving the coding region for the recombinant polypeptide to be produced; and d) transcription termination signals and drawn to a method of producing said polypeptide.
- II. Group II: claim 14 and 15-18, drawn to a fusion polypeptide obtained by the method of any one of claims 10 to 13 and drawn to a purification tag comprising a sortase gene product.
- III. Group III: claims 19-22, drawn to a method of inducing and/or enhancing an immune response to an antigen of interest, the method comprising administering the antigen of interest with a sortase gene product.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

1. The technical feature of Group I is the expression construct for the production of recombinant polypeptides and the method of producing said polypeptide , which construct comprises an expression cassette consisting of the following elements that are operably linked: a) a promoter; b) the coding region of a DNA encoding a sortase gene product as a purification tag sequence; and c) a cloning site for receiving the coding region for the recombinant polypeptide to be produced; and d) transcription termination signals.

This technical feature is anticipated by Ton-That et, al. PNAS October 26, 1999 vol. 96 no.22 p. 12424-12429 as evidenced by pQE-30 vector (The QIAexpressionist. Handbook for high-level expression and purification of 6x-his tagged proteins, Qiagen, June 2003). Ton-That teaches the cloning of a sortase (srtA) gene into the Bam HI site of the plasmid pQE30 for protein expression (p. 12425 left column last paragraph). Said expression construct of Ton-That comprises the following elements that are operably linked a) a T5 promoter (see attached map of pQE30 vector; b) followed by sortase gene cloned into BamHI site (see map of pQE30); and c) a cloning site for receiving another coding region of a recombinant polypeptide (see other restriction sites after BamHI site of pQE30); and d) transcription termination signals (see map of pQE30 for transcription termination region following multiple cloning site).

2. The technical feature of Group II is the fusion polypeptide obtained by the method of Group I and the a purification tag comprising a sortase gene product.

3. The technical feature of Group III is the method of inducing and/or enhancing an immune response to an antigen of interest, the method comprising administering the antigen of interest with a sortase gene product.

Group I lacks unity with Groups II-III because the technical feature of Group I is anticipated by the art (see above) and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

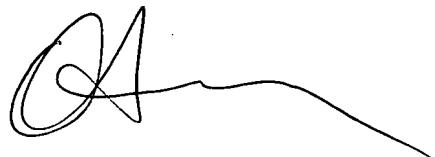
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

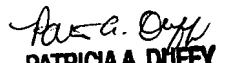
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Oluwatosin Ogunbiyi
Patent Examiner
Art unit, 1645


PATRICIA A. DUFFY
PRIMARY EXAMINER